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10/686,347	10/14/2003	Vincent K. Gustafson	129-US	7189

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EXAMINER	
JOYNER, KEVIN	
ART UNIT	**PAPER NUMBER**
1744	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/686,347	GUSTAFSON ET AL.	
	Examiner	Art Unit	
	Kevin C. Joyner	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *13-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,23 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

FINAL ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-12, 23 and 24, drawn to a method for preparing a microfluidic device, classified in class 422, subclass 4.

II. Claims 13-22, drawn to a microfluidic system, classified in class 422, subclass 100.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions of Group I and Group II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process as claimed can be practiced by another and materially different apparatus. More specifically, the process can be practiced by an apparatus that does not include a distribution network or a plurality of columns, wherein a vacuum source is in periodic fluid communication with the columns. The apparatus may include a plurality of horizontal rows, wherein the vacuum source is never in communication with any of the rows, and is only in fluid communication with the inlet and outlet of the apparatus.

3. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

1. During a telephone conversation with Mr. Vincent Gustafson, a provisional election was made with traverse to prosecute the invention of Group I, claims 1-12. Affirmation of this election must be made by applicant in replying to this Office action. Claims 13-22 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. However, because the applicant did not provide a response to the restriction in the reply filed June 9, 2007, then the Election was considered to be made **without** traverse.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-3, 5, 9,10, 23, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blackburn (U.S. Patent No. 6,875,619) in view of Harrison et al (U.S. Patent No. 6,632,619).

Blackburn discloses a method for preparing a microfluidic device for operation, the method comprising the steps of:

providing a microfluidic device having a fluidic inlet, at least one fluidic outlet, a plurality of microfluidic channels disposed between the fluidic inlet and the fluidic outlet as disclosed in column 12 lines 1-15, and separation media disposed within at least one microfluidic channel of the plurality of microfluidic channels as disclosed in column 28 lines 37-38, between the fluidic inlet and the fluidic outlet, with at least one microfluidic channel of the plurality of microfluidic channels containing a gas as disclosed in column 72 lines 42-48;

providing a vacuum pump (concerning claim 9) in at least periodic fluid communication with at least one of the fluidic inlet and the at least one fluidic outlet as disclosed in column 72 lines 52-64;

providing a liquid pump (concerning claim 10) in at least periodic fluid communication with the fluid inlet as disclosed in column 23 lines 59-66;

evacuating the gas from the microfluidic device using the vacuum source as disclosed in column 72 lines 42-64; and

introducing a liquid into the microfluidic device through the inlet using the liquid pump as disclosed in column 47 lines 34-45. More specifically, the reference states that

the pump is used to transfer both charged particles and bulk solvents to provide fluid flow in the channels of the device in column 47 lines 13-23, and that in the preferred embodiment, a electroosmotic pump is used because it is particularly useful for liquids in column 47 lines 34-46.

Blackburn does not appear to disclose evacuating the gas from the microfluidic device using a vacuum source, and following the gas evacuation step, introducing a liquid into the microfluidic device through the inlet using the positive pressure source. Harrison discloses a method of using a microfluidic system. The method includes providing a microfluidic device having a fluidic inlet, at least one fluidic outlet, a plurality of microfluidic channels disposed between the fluidic inlet and the fluidic outlet as shown in Figures 1-4, with at least one of the fluidic channels containing a gas;

providing a vacuum source in periodic fluid communication with at least one of the fluidic inlet and the at least one fluidic outlet;

evacuating the gas from the microfluidic device using the vacuum source as disclosed in column 19 lines 46-51;

providing a positive pressure source in at least periodic fluid communication with the fluidic inlet; and

introducing a liquid into the microfluidic device through the inlet using the positive pressure source as disclosed in column 10 lines 48-53. The reference continues to disclose the steps of evacuating the gas from the microfluidic device using the vacuum source prior to introducing a liquid into the microfluidic device (column 19, lines 40-50; See **Response to Arguments** below) in order to remove any dust or debris that may be

blocking the flow paths. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Blackburn to evacuate the gas in the device prior to introducing the liquid in order to remove any dust or debris that may be blocking the flow path as exemplified by Harrison.

Concerning claim 2, Blackburn continues to disclose that the method further includes the step of temporarily sealing the fluidic inlet prior to the evacuation step in column 72 lines 58-61.

Regarding claim 3, Blackburn does not specifically disclose the type of gas that is evacuated from the channels. Harrison further discloses that the gas is air in column 19 lines 46-51. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention that the step of providing a vacuum source to evacuate a gas is used to evacuate air in the method of Blackburn, as is a commonly evacuated gas from a microfluidic device as exemplified by Harrison.

Concerning claim 5, the reference continues to disclose that the device in the method further comprises a hydrophobic frit material in column 62 lines 10-16. More specifically, particles of the glass-ceramic materials are frit materials.

Regarding claims 23 and 24, Blackburn does not appear to disclose that said gas evacuation is performed through the at least one fluidic outlet that is externally accessible and is adapted to permit liquid flow therethrough. Harrison continues to disclose that said gas evacuation is performed through the at least one fluidic outlet that is externally accessible and is adapted to permit liquid flow therethrough (column 19, lines 40-65; Figures 5B and 8). More specifically, the steps of evacuating the gas and

introducing the liquid occur in the same flowpaths in order to simplify the device. Therefore, the gas evacuation is performed through the fluid outlet that is adapted to permit liquid flow therethrough. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Blackburn to perform said gas evacuation step through the at least one fluidic outlet that is externally accessible and is adapted to permit liquid flow therethrough in order to simplify the device and reduce the number of fluidic outlets as exemplified by Harrison.

3. Claims 4 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blackburn (U.S. Patent No. 6,875,619) in view of Harrison et al (U.S. Patent No. 6,632,619) as applied to claim 1 above, and further in view of Strand et al. (U.S. Application No. 2002/0199094).

Blackburn in view of Harrison is relied upon as set forth above. Blackburn in view of Harrison does not specifically disclose that the separation media is of the stationary phase type. Strand discloses a method of separating fluids in a cartridge using separation media. The method further discloses that the separation media comprises stationary phase material that allows for reversible adsorption of species in the fluid in paragraph 10. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Blackburn in view of Harrison to comprise the separation media of stationary phase material in order to allow for the reversible adsorption of the species in the fluid as exemplified by Strand.

Concerning claim 11, Blackburn in view of Harrison does not disclose that the liquid introduction step includes supplying liquid pressurized to at least about 100 psi to

the microfluidic device. Strand however discloses that the liquid introduction step includes supplying liquid pressurized to at least about 100 psi to the microfluidic device in paragraph 13 of the reference. Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to include the step of supplying the liquid to the microfluidic device at a pressure of at least 100 psi in the method of Blackburn in view of Harrison, as such is a commonly known operating pressure as exemplified by Strand.

4. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Blackburn (U.S. Patent No. 6,875,619) in view of Harrison et al (U.S. Patent No. 6,632,619) as applied to claim 1 above, and further in view of Dantsker et al. (U.S. Patent No. 6,499,499).

Blackburn in view of Harrison is relied upon as set forth above. Blackburn in view of Harrison does not appear to specifically disclose that the liquid is an organic solvent of ethanol. However, solvents comprising ethanol is a commonly known and commercially available liquid used in microfluidic devices. Dantsker discloses this in a method for the flow control in multi-stream microfluidic devices. The microfluidic device comprises a plurality of inlets and outlets along with a plurality of microfluidic channels as shown in Figures 1-3. Dantsker continues to disclose that the liquid introduced into the microfluidic device is a solvent comprising ethanol. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to utilize a solvent comprising ethanol in the method of Blackburn in view of Harrison, as is a known commercially available and widely used liquid in microfluidic devices as shown by Dantsker.

5. Claims 7, 8, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blackburn (U.S. Patent No. 6,875,619) in view of Harrison et al (U.S. Patent No. 6,632,619) as applied to claims 1 and 2 above, and further in view of McNeely et al. (U.S. Patent No. 6,607,907).

6. Blackburn in view of Harrison is relied upon as set forth above. Blackburn in view of Harrison does not appear to disclose that the method further comprises the step of disallowing fluid communication between the vacuum source and at least one of the fluidic inlet and the at least one fluidic outlet prior to the liquid introduction step. McNeely describes a method for controlling the airflow in microfluidic circuits. The method includes a microfluidic device with inlets, outlets and microfluidic channels as shown in Figures 4-6, including a positive pressure source (2), a vacuum source (56 and 57), and an operating valve (36). The method further describes that the positive pressure source introduces a liquid to the microfluidic channels (column 65 lines 66-67), and the vacuum source evacuates gas from the channels (column 6 lines 6-25). The method further discloses the step of sealing the outlet by operating a valve by disallowing fluid communication between the vacuum source and at least one of the fluidic inlet and the at least one fluidic outlet prior to the liquid introduction step as disclosed in column 5 lines 60-67. More specifically, the valve is closed once the pressure is reached in the device, which disallows fluid communication between the vacuum source and the inlets and outlets. The pump is then turned on to return any liquid that may have been displaced, thus introducing it to new parts of the channels in the device. Therefore, it would have been obvious to one of ordinary skill in the art at

the time of the invention to modify the method of Blackburn in view of Harrison to include the step of disallowing fluid communication between the vacuum source and at least one of the fluidic inlet and the at least one fluidic outlet prior to the liquid introduction step by sealing it with a valve in order to maintain the optimal pressure in the device as exemplified by McNeely.

Concerning claim 8, Blackburn discloses a method that includes temporarily sealing the fluidic inlet prior to the evacuation step. Blackburn does not appear to disclose operating a valve during the temporary sealing step. It is known in the art to operate a valve during the step of sealing in a method however. McNeely discloses this, wherein a valve is operated during the temporary sealing step in order to seal an area in the microfluidic device. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Blackburn in view of Harrison to include operating a valve during the sealing step, as such is a common method to seal areas in the art as exemplified by McNeely.

Concerning claim 12, Blackburn continues to disclose that the microfluidic device has a plurality of fluidic outlets adapted to permit liquid flow (column 30, lines 40-43) as shown in the Figures. Blackburn does not specifically disclose that the vacuum source is in fluid communication with a certain number of the fluidic outlets, or that the gas is evacuated from the device through more than one outlet. However, McNeely discloses that the method including the microfluidic device has a plurality of fluidic outlets and that the vacuum source is in fluid communication with the outlets, wherein gas is evacuated from the device through the outlets in Figure 6 and column 6 lines 19-25. More

specifically, the vacuum source is the pressure regulators (56 and 57) where air is passed from the channel (referenced as an air duct (49)) to channel (referenced as an air duct (50)) and out of the device by the pressure regulator (56). As the air passes across the channel (51), it will proceed through the channel and out of the outlet (53), thus providing a plurality of outlets where gas is evacuated from by the vacuum source (56 and 57). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention that the method of Blackburn in view of Harrison would evacuate gas from a plurality of outlets by using the vacuum source in order to expedite the process of evacuating the gas from the channels as exemplified by McNeely.

Response to Arguments

1. Applicant's arguments with respect to claims 1, 2, and 4-12 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's principle arguments are:

(a) Blackburn in combination with either Strand, Dantsker, or McNeely does not teach the removal of gas prior to introduction of liquid into a microfluidic device.

The argument is moot in view of the new grounds of rejection.

2. Applicant's argument filed June 9, 2007 with respect to claim 3 has been fully considered but they are not persuasive.

Applicant's principle arguments are:

(a) Blackburn in combination with Harrison does not teach the removal of gas prior to introduction of liquid into a microfluidic device.

However, as clearly disclosed in column 19, lines 40-50 Harrison discloses the step of removing a gas prior to introduction. More specifically, the reference discloses that the microfluidic flow paths are first vacuumed in order to remove dust and other debris particles that may be lodged in the flow paths causing blockage. Following the vacuum, a saline solution is then added to the flow paths. Since the reference expressly discloses dust and dust is only available in a gas, then the reference teaches removal of a gas with the step of introducing a liquid to the flow paths afterward.

Conclusion

3. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin C. Joyner whose telephone number is (571) 272-2709. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GLADYS JP CORCORAN
SUPERVISORY PATENT EXAMINER

KCJ